

PLAN OF PROCEDURE

FOR STUDY OF

ARTERIOSCLEROTIC HEART DISEASE

AMONG

NAVY AND MARINE CORPS MEMBERS



PHYSICAL QUALIFICATIONS AND MEDICAL RECORDS DIVISION

NAVY DEPARTMENT
BUREAU OF MEDICINE AND SURGERY
OCTOBER 1962

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TABLE OF CONTENTS

<u>SUMMARY OF PLAN</u>	<u>PAGE</u>
INTRODUCTION	1
Nature of the Sample	1
Current Practices with Respect to Disposition of ASHD Patients	2
I. OBJECTIVES OF STUDY	4
Basic Purpose of this Investigation	4
Broad Objectives	4
Specific Objectives	5
Necessary Qualifications	7
Further Relationships Worth Exploring	8
II. PROCEDURAL PLAN FOR DATA PREPARATION	12
Phase A: Planning	12
Phase B: Data Preparation Procedure	17
Phase C: Interim Review	28
Enclosures	
1. "Revised Schedule of ASHD Diagnostic Patterns"	1E
2. Criteria for Acceptance of the Several Types of ASHD Patterns.	2E
3. Specific Items Proposed for Trans- cription:	10E
a) Essential Items Related to ASHD	10E
b) Physical Examination Measurement Data	11E
c) Optional but Desirable Additional Items	12E
Tab A: Description of Basic Sample, Its Limitations and the Control Sample	1A
Tab B: Specific Types of Data to be Evaluated	1B

SUMMARY OF PLAN

This document is a plan of procedure for conduct of a study of arteriosclerotic heart disease (ASHD) among Navy and Marine Corps members. We plan to combine a follow-up analysis on present status with an analysis of first and later episode symptoms, clinical decisions, laboratory tests, Electrocardiograms and physical examination measurements. The latter measurements and other pertinent information in the medical record will be analyzed for trends throughout the patient's whole Navy experience in relation to the development and outcome of this disease.

The attached plan includes the character of the ASHD sample now available, purpose and proposed objectives, specific types of data to be transcribed from medical records and later evaluated, and a project administrative plan with the specific steps required. The latter plan covers only Phases A and B ("Planning" and "Data Preparation" Phases) for project work during the next six to eight months. It does not cover details of the proposed future data analysis except in outline skeleton form. The details must wait until we have assembled and tabulated some data.

In general, however, we wish to evaluate the time periods exhibited by the development of the disease, the frequency of occurrence of a number of usual ASHD diagnostic patterns, the related time intervals associated with various physical activity/administrative status changes necessitated by the disease, and the various physical and medical factors related to the disease progression for which we have available data.

This will be accomplished by uniform transcription of pertinent data from the medical records (including, we hope, follow-up data from the patient on his present status if alive), its translation into number codes and punch-card form and cross tabulation of these data into what appear now to be interesting relationships. The latter stages will, of course, have to await the completion of the very time-consuming data preparation now being initiated. However, in order to be sure that we are collecting the proper data and in a manner convenient for later analysis, we are now presenting this plan.

PLAN OF PROCEDURE

For Study Of ARTERIOSCLEROTIC HEART DISEASE

Among Navy and Marine Corps Members

INTRODUCTION

Basic purposes, broad objectives and proposed approach for this ASHD study have been discussed briefly in an earlier planning document ^{a/}. More detailed discussion on these aspects are given in Chapter I of this present document.

Navy Department medical records on hospital patients have been maintained intact for many years as have recurring medical examination results for Navy service personnel. These records are, therefore, a fertile source of statistical information on disease incidence and related factors among these personnel and on historical data bearing on these diseases and their development. Arteriosclerotic heart disease is among those conditions which cause much disability among older enlisted men and officers.

Nature of the Sample

We are proposing to tap this information in a follow-up study of ASHD patients ^{b/}. This investigation will be initiated using approximately 550 cases of service members who first developed this specific diagnosis (ASHD) or closely related ones ("myocardial infarction" and "coronary artery thrombosis") while on active duty in 1950-51.

^{a/}"Objectives and Suggested Plan of Procedure for the Heart Study", Navy Bureau of Medicine and Surgery, PQ &MR Division, 12 July 1962.
^{b/}More recently called atherosclerotic heart disease in the newer International Terminology and also referred to in earlier cardiology textbooks as coronary artery heart disease or coronary heart disease (or CHD).

This sample and the control sample are described in detail in TAB A.

In addition to being obtained originally from a carefully screened group of relatively young and healthier-than-average men, this ASHD sample is a relatively small one, particularly for the extensive statistical investigation purposes we have in mind. It is, moreover, a pre-selected sample in itself, consisting initially, as we have indicated, only of persons who were still on active duty in 1950-1951. Among the enlisted men, in 1950 two-thirds had less than 30 years of service i.e., they generally enlisted after 1920 and, therefore, were usually less than 50 years old. Among the officers, in 1950 they appeared to be generally older; two-thirds were over 50 years of age but were still among age groups generally considered active and fit in the Navy at that date. About half of these 1950-1951 cohort persons appear now to have died in the ensuing 11 years since 1950 — the greater portion of course being in the older age brackets when they died.

Current Practices with Respect to Disposition of ASHD Patients

The Manual of the Medical Department in effect requires that members of the Naval Service hospitalized for a serious condition such as ASHD be evaluated by either a "Board of Medical Survey" or by a "Medical Board." Depending on length of service, if the medical officer in charge of the member's case believes the patient able to perform limited duty without aggravating his ASHD condition, generally his case is referred to Boards of Medical Survey. Those evaluated by a Board of Medical Survey as capable of limited duty are returned to such duty provided their services can be utilized in that status.

Otherwise they are subsequently ordered before a Physical Evaluation Board (PEB) with the report of the Medical Survey Board used in lieu of a Medical Board report.

In practically all cases those members initially evaluated by a Medical Board are referred directly to a PEB. If a PEB recommendation of unfitness is approved by the Secretary of the Navy, the member's name is placed on the Temporary Disability Retired List, (TDRL) in most instances. While carried on the TDRL (which legally may not exceed a period of 5 years) a member usually is re-examined every 18 months until such time as it is determined that his disability has stabilized or the 5 year period has expired. Upon a final evaluation that the member is permanently unfit his name usually is placed on the Permanent Retired List. In a small number of cases where the impairment initially is severe and prognosis poor the member's name may be placed on the Permanent Retired List within a short time after effecting such a determination.

Occasionally the Secretary of the Navy may approve the recommendation of a PEB that a member with ASHD be returned to duty. This occurs when his condition appears to be progressing well and he is asymptomatic. This Bureau's policy, however, as well as that of the Surgeon General's representative on the Physical Review Council, is to consider a confirmed diagnosis of ASHD to be incompatible with return to full duty.

In summary, for the bulk of ASHD patients, the member goes on temporary retirement and remains in that status until approximately 5 years have elapsed. At this point his retirement becomes permanent.

I. OBJECTIVES OF STUDY

Basic Purpose of This Investigation

The purpose of this statistical investigation is to explore the occurrence of this disease among Navy and Marine Corps members, to assay duty potential of the affected members, to characterize the variety of forms the disease takes, and to attach time periods to the progression of the disease in its several forms — relating these to the administrative observation waiting periods now observed. The present 5 year practice regarding the use of TDRL usually involves several hospitalizations, the time of many doctors and other medical personnel, and the time and attention of navy administration officials. Moreover, it involves some actual physical disruption in the patient's restricted activity status and no doubt entails a certain amount of emotional stress to him.

This 5 year waiting period is perhaps somewhat arbitrary and without much substantiated factual basis in the natural history of the disease among naval service members^{c/}. The 18 month re-evaluation periods are likewise somewhat arbitrary and based principally on a reasonable judgement by the Department as to their need. We hope to bring out more closely the variety of signals which might be used as a scientific rather than an arbitrary basis for making temporary or permanent retirement status changes.

Broad Objectives

1. To obtain a large body of statistical data relating to the occurrence of ASHD among Navy and Marine Corps members and the related time periods in the progression of this disease.

c/ This 5 year period appears to have been based on civilian experience.

2. To obtain statistical data sufficient to draw valid conclusions as to the relative occurrence and as to the proper time points for determining:

- (a) whether a Navy member has a serious ASHD condition;
- (b) consequently, whether he should be retired, be given limited duty or, if his condition is not significant, be returned to full duty;
- (c) at what point a resulting retirement should be temporary (for observation) or permanent;
- (d) if given limited duty, what restrictions on his activity and duties are appropriate? And how long should this be continued?
- (e) what medical signals should be watched in the ASHD patient's future as an administrative guide to possible changes in his condition and physical status ^{d/}?

3. To obtain statistical data sufficient to determine what are the time lapses now being observed in the legal/administrative machinery to effect the necessary changes in status. In what way, if any, do they differ from the foregoing medically determined stages and intervals?

4. To obtain further epidemiological evidence regarding the development of this disease.

Specific Objectives

The following specific objectives are the ones which we would ideally expect to answer by analysis of the proposed data collections:

- 1. What is the relative frequency of each of the frequently occurring ASHD pattern types?

d/ That is, what are the important signals, which pinpoint important changes in the patient's condition, for administrative use?

2. To what mortality and morbidity rates in naval military personnel do these frequencies correspond - by age group, etc.?
3. To what survival periods and survival rates do they correspond?
4. What is the average patient age at which the first episode of each pattern type appears? What is the corresponding age distribution?
5. What is the time period between each of the foregoing episodes and the next one?
6. What is the survival period beyond the last episode?
7. How do the foregoing vary with the varying complications and varying symptoms?
8. Does the first episode character set the tone for the whole disease progression, or is the latter independent of the first episode? Is it dependent upon any episode other than the first?
9. At what time intervals following the first episode can one definitely say that the disability is permanent?
10. At what time intervals, therefore, should the ASHD patient be adjudged as permanently unfit for duty? Temporarily unfit? Fit for limited duty?
11. What are the conditions under which it is not possible to make the foregoing determinations? Or is it possible at all, other than arbitrarily?
12. When the permanent disability determination period has been established, can one devise a practical impairment index?

13. Will this latter change rapidly or slowly and in consequence can the corresponding disability rating be frozen at an early date or must it remain tentative and subject to extensive further change?
14. What are the important symptoms and signs establishing the seriousness of the episode?
15. What are the precursive signals (if any) warning the doctor and patient (if he is informed ahead of time) that ASHD is impending?
16. What factors appear to be directly related to a recognized ASHD attack?
17. What factors, commonly thought to be related, actually show no relationship (or very little)?
18. Are there several different types of persons predisposed to ASHD? Or for which ASHD is a frequently occurring condition?
19. Are there activity types, job types, experience types, etc. that are predisposing to ASHD? Or for which ASHD is a frequently occurring condition?
20. What early signals and/or symptoms should be watched in the medical record with a view toward predicting which patients are likely to develop ASHD? What time intervals are involved? What proportions of cases would be spotted by this device? What should be done when these signals appear?

Necessary Qualifications

Some of the foregoing objectives, however, probably will not be achievable — for a variety of reasons, such as:

- (a) if there were insufficient data in certain of the age groups, ASHD pattern types, duty status classes, etc.;
- (b) if there were inconclusive statistical evidence in comparisons between ASHD or other classes as determined by the analysis (although the data bulk was sufficiently large under the usual circumstances);
- (c) if the relationships between ASHD severity and factors expected to be related were too indefinite or indirect to allow the logical deduction of any valid conclusions regarding their relationships;
- (d) if there were infeasible data collection on some of the data items or for some of the ASHD cases (for administrative, or operational reasons, etc.).

Further Relationships Worth Exploring

Current and Recent Hypotheses. A number of hypotheses regarding the genesis of ASHD have been suggested by various investigators working on the problems related to this disease. Among them are the following:

- *1. That ASHD genesis is related to blood cholesterol levels ^{e/}.
- 2. That ASHD episodes are induced by explosive hypertensive episodes, or by emotional crises, or by extreme fatigue or by abnormal exertion;
- 3. That ASHD is a disease predominantly occurring among short, stocky, fat persons (the "lateral" type) rather than among tall, thin persons (the "vertical" type);

e/Investigation of data on the starred hypotheses is not possible in this ASHD sample because tests relating to these conditions were not generally in use during 1950-1951. This problem is discussed in a later chapter.

*4. That ASHD incidence is associated with high levels of all serum lipids (not just cholesterol);

*5. That excess quantities of "saturated" fatty acids in the blood serum induce arteriosclerotic heart changes.

Observations Among Navy ASHD Patients. The foregoing are only some of the hypotheses which have been advanced. Very little basic information, however, is known actually about the real causes and etiology of this disease ^{f/}. Casual observation of the clinical records of a substantial number of ASHD patients suggests certain apparent relationships which we feel are worth investigating with refined statistical techniques where this is feasible. We feel the opportunity to make a careful analysis of these facts about Navy ASHD patients may therefore be rewarding. Such observation suggests that among ASHD patients, the following may be of interest: ^{g/}

(a) There appears to be a substantial proportion of ASHD patients with hypertension; this appears casually to be a "preponderance" among the age groups above middle age but, nevertheless of frequent occurrence among all age groups.

(b) ASHD Navy patients appear as a group to be generally under the average in height and over the average in weight — the latter, by substantial amounts.

^{f/}The literature of this disease is prolific and full of apparent contradictions and differences in opinion.

^{g/}These observations are not original with us; most of them have been noted frequently in the literature. Controlled data on these effects are less numerous, however, and more ambiguous in their interpretation.

(c) Many overweight ASHD patients appear to have put on weight very quickly when they approached middle age; they appear to maintain this overweight in spite of frequent contrary medical advice; but may lose this excess weight quickly under a controlled hospital reducing diet following an ASHD episode. Moreover, they appear to regain this weight quickly when they are released under their own diet control.

(d) ASHD patients may apparently have a larger than usual accident proneness rate and may be subject to a larger variety of joint-related disabilities and accidents. There are also perhaps some patients more prone to other vascular disabilities associated with generalized arteriosclerosis affecting other areas of the body.

(e) Frequently ASHD patients may appear to show episodes of acute emotional stress. These occur usually either in relation to their adjustment to various changed circumstances of living (particularly in Navy situations where the economic adjustment may be severe) or to the recurrences in acute ASHD episodes. It is not clear which is cause and which is effect but this emotion relationship may be interesting to explore.

(f) There appear to be a small but significant group of borderline cases who apparently have only subjective ASHD symptoms; these may be transient and/or controversial in nature. The status of these members is the subject apparently of much indecision among the examining physicians as to the patient's real condition. This disease, under the foregoing circumstances, when most of the diagnostic signs are subjective, appears to be thought occasionally a vehicle for malingerers. Conclusive statistical evidence should be obtained as

to the reality of these types of ASHD cases and of their real status.

Factors We Wish to Attempt to Correlate

In view of the foregoing casual observations and of the various hypotheses currently or less recently put forth, we think the following - among others - should be analyzed: age incidence and severity vs blood pressure; age incidence and severity vs excess weight (probably measured as a weight/height index ratio); age frequency and rapidity of recurrence vs frequency of emotional or other adjustment crises; and age frequency among specific Navy occupations vs frequency of borderline or "suspect" cases; age frequency vs occurrence of prior pertinent non - ASHD illness.

II. PROCEDURAL PLAN FOR DATA PREPARATION

This present project operation plan covers the first two "phases" for this project: A) "The Planning Phase" and B) "The Data Preparation Phase" ^{h/}. An additional planning document will be supplied late next spring or summer covering proposed remaining phases: "Interim Review", "Analysis" and "Final Report".

PHASE A: PLANNING

Preliminary Case Review

The Planning Phase includes a preliminary case review to familiarize us with the kinds of data to be expected, the types of ASHD cases which usually occur in the Navy and some idea of the way these cases are handled in the Navy Hospital System. This review has been completed. In this connection we have also completed a series of trial data recordings -- using a number of different samples of recording form types. This was done in order to obtain a rough idea of the size of the transcription task ahead and of the requirements of format, space, sequence, etc. needed for this purpose. The trial records have resulted in the design of a series of provisional forms which are discussed at length in a later section ^{i/}.

Procedure Planning Stage

This step follows the case review and its product constitutes

^{h/}These were referred to in an earlier project proposal: "Objectives and Suggested Plan of Procedure for the Heart Study", 12 July 1962.

^{i/}Samples of these forms are available on request. They will no doubt require further revision as we gain experience in using them.

this present document. This whole plan is intended as an overall guide in conduct of the project. It will also supply persons reviewing the project operations with an approximate idea of the proposed extent of data collection, transcription, calculations and tabulation operations embodied in phases A and B of the project. This present planning document has been reviewed by the PQMR Division medical staff and will be reviewed by several members of an informal advisory group and by higher authority. Changes recommended by these persons will be incorporated when feasible.

Statistical Clerk Training Period

This training step will require at least a month (perhaps several) depending upon the ability of a new clerk to pick up ASHD terminology and the classification systems and to learn the transcription, recording and calculation procedures we will be using.

The pilot run recording discussed below and selection of the control cases will also be undertaken during this time, as well as the continued review of further ASHD cases by the project analyst. The end of the clerk training period will constitute the end of Phase A.

Pilot Run Recording

The provisional recording forms, mentioned earlier will also be used during this training period for the first 75 to 100 cases in a "pilot run". This test will have a three fold purpose: 1) to test the present form revisions in actual production practice; 2) to familiarize our transcribing clerk with the types of recording problems encountered and how to solve them, and the locations of the pertinent data; and 3) to supply us with some very rough-and-ready statistics

regarding the basic ASHD sample.

Provisional Recording Forms

The forms developed so far are described below. They will be revised as necessary following the pilot run.

a) Main Transcript Card: for basic statistical and identification data plus data on the first major ASHD episode; this card also includes some summary information for all the episodes.

(Sample: Yellow card $8\frac{1}{2}$ x $13\frac{1}{2}$, ASHD Form 1, 8/12/62).

b) Subsequent Episode Transcript Card: for use in recording data for all subsequent episodes, 1 new card for each episode (including the last). (Sample: white card 8.5 x 13.5, ASHD Form 2, 8/12/62).

c) Control Card: for project administration control and cross-indexing between Serial Number and Study Number. A separate study number of 3 digits is to be used to effect a continuous series control count and to avoid the punch card use of 7 digit serial numbers for intercard identification and IBM card sorting. This card also has provision for recording specific project administrative step dates so that we can tell quickly how our recording task is progressing.

(Sample: Yellow card 8 x 10.5, ASHD Form 3, 8/17/62).

d) Physical Examination Profile Record Form: for recording physical measurements in profile form taken at periodic physical examinations. It will also have provision for interpolating corresponding measurements at episode start dates, so that some type of mathematical relationship may be calculated to show the lineup between "profile" data and corresponding "episode" data. We hope to use this device to tie the two series together. This is necessary because the dates hardly ever

correspond closely. It would be difficult, otherwise, to say what a man's basal weight and blood pressure were at time of admission, if one were dependent only on data recorded on admission during a major episode. (Sample: Blue card 8.5 x 11, ASHD Form 4, 9/12/62).

e) Episode History Summary Card: for recording brief serial summaries of ASHD episodes, with abstracts of clinical notes and other data pertinent to the episode in question and to the patient's whole ASHD history. Space is provided for 3 episodes per card which will take care of the bulk of the ASHD patients. For those for whom 4 or more episodes have occurred a second card will trail the first one.

(Sample: White card 8.5 x 11, ASHD Form 5, 9/12/62)

f) Crucial Date Summary Card: for recording a very brief reference to each crucial date in a patient's ASHD history. These dates and related diagnoses, disability ratings, duty status, etc. will enable us to compute pertinent time intervals and their distributions for major episode duration, survival time, natural and service ages, disability and duty status changes, and for similar important time intervals. (Sample: Green card 8.5 x 14, ASHD Form 6, 9/25/62).

g) ASHD History Coverage Schedule: for recording applicable dates relating to what part of the ASHD history is covered by hospitalization records and what part is not. The latter obviously will require further follow-up procedure.

(Sample: Pink card 8.5 x 13, ASHD Form 7, 10/12/62).

Value of the Recording Forms

These transcription forms will provide the following:

- 1) They will facilitate card punching and uniformity in data recording.

- 2) Provide a ready means for answering certain special questions quickly and as they arise -- without recourse to the elaborate machine tabulation procedures which will follow ^{j/}.
- 3) Provide an ASHD medical history summary in terms of the analysis approach and of the types of data we are considering. These summaries will be carefully screened, must be brief, and will have all the facts pertinent to the patient's condition in their proper order.
- 4) This episode history summary will help explain peculiarities in the statistical data which may arise.
- 5) These summaries will be useful in classifying each patient by ASHD pattern type and by American Heart Association functional and therapeutic classes, as well as for aid in making any other medically-related decisions in classification.
- 6) The control card will allow us to maintain a continuous control on the status of the data recording and on its completeness and will provide quick counts for administrative progress and status reports.

^{j/} Such questions usually arise in the course of most statistical investigations and cannot always be foreseen in the planning procedure, but they usually have to be answered.

PHASE B: DATA PREPARATION PROCEDURE

Basic Study Data Transcription

The medical history and statistical information on ASHD is scattered in the patient medical records among a large number of assorted documents -- usually arranged chronologically with the most recent first. However, these documents are frequently in some other order. In addition to the bulk of paper to leaf through, the documents have legal status and for medical administrative purposes are confidential. All data taken from them must be treated confidentially, with the whole record remaining intact. To accomplish this selective abstract of ASHD data, we plan to transcribe the pertinent information to the previously described series of transcript card forms under closely controlled protocol rules. Provisional form samples are available for inspection.

Types of Data Transcription from Medical Records

Transcription of ASHD medical data and history has been discussed in several previous sections. Information on items shown in "List of Essential Items" in Enclosure 3a should be available for every ASHD patient. Those marked with asterisks (*) on that list and those on Enclosure 3b ("List of Physical Profile Items") should also be obtainable for control members as well as for ASHD patients. Items on Enclosure 3c ("Optional But Also Desirable Data") are those for which we anticipate collection problems of one kind or another -- chiefly lack of data on specific cases -- or about which there is a real question as to their ultimate statistical value. We shall attempt, during the recording of the data for the first 100 cases, to obtain

all items on all three lists and will decide at the end of this time how feasible each is to obtain. At this point a final decision will be made regarding the permanent operational status of each.

Supplemental Navy and Veterans Administration Data

In addition to regular data from the Navy medical records, included in the lists mentioned above, we are proposing to obtain additional information from Navy's Bureau of Personnel on certain items related to the patient's personnel record. These are: (1) the type of Navy job activity held by the patient during the major part of the three years prior to his first ASHD episode ^{k/}; (2) the presence of combat stress or war area experience during the same time; and (3) any elements of the fitness evaluation report which might add to or explain psychological/emotional stress during this same critical period.

For periods of missing Navy Medical record coverage, we will also attempt to obtain from VA and other military hospital medical sources, the data corresponding generally to Navy medical record information, as discussed later.

Supplemental Navy Hospital Record Sources

For certain of these cases, the Veterans Administration will have borrowed the entire Navy file or a large part of it. This will

^{k/}This job activity should reveal whether he had a desk job or a standing/moving/exertion job and if the latter, some idea of the extent of the related exertion. That is, we want to know whether or not he regularly had to use his lifting/pushing/pulling muscles. If the former (desk job), we want to know whether he was subjected to unusual responsibility or emotional stress of one kind or another.

require its return and a corresponding control check to see that this record is complete.

In addition, BuMed's central office medical history is largely made up of abstracts and summaries of the actual Navy hospital clinical records. When these summaries are missing, deficient or lacking on certain critical statistics, it will be necessary to obtain the full hospital clinical record -- either from the St. Louis storage center (if it is there) or from the pertinent Navy hospital.

Gaps in the Medical Record

As long as an ASHD patient is under surveillance of the Navy's physical evaluation board system (as long as he is on TDRL), we will have information on subsequent hospitalization in his medical record. For most 1950 - 1951 cohort individuals, this covers experience into 1955 - 1956. However, some patients are placed on permanent retirement very shortly after developing ASHD. For these we have no subsequent record unless they voluntarily sought medical care at a military activity. Likewise, for all patients placed on the permanent retired list in 1955 - 1956, we have no subsequent record unless it represented a voluntary effort by the patient to obtain medical care from the military.

Follow-up Procedure and Questionnaire

Since these patients also have access to VA hospitals as well as to private and local public hospital facilities, it is also necessary that we include follow-up procedure to cover this additional experience if it occurs. Most of these patients are not well off financially and will therefore seek subsidized medical care if available

-- either through a military hospital or the VA in their own neighborhoods. If hospitalized in a military hospital, we will have a record or reference to it. For VA, however, the record may be incomplete. We propose a check, therefore, with VA hospitals in this manner:

1. For live patients only, we will select those with obviously incomplete records, sort them by residence and furnish the regional VA office with a list of names and serial/claim numbers. VA offices will be requested to supply copies of hospital records for those with recorded hospital visits. For the remaining patients with no VA or military record since permanent retirement, we plan to send a follow-up letter to the patient along with his regular retirement pay check, asking for hospitalization dates and places and granting to the hospitals or the private physician authority to release requested information. From this we hope to obtain on a "no cost" basis a brief medical history subsequent to permanent retirement as well as the patient's present status.

2. For patients now dead, we will have a death certificate record, with date, place, name of physician (if any) and probable cause of death. Where the time interval is long between the patient's last Navy hospitalization or other live Navy reference and his death we will try to approach his family physician or the local hospital (if death occurred in the latter) to obtain also on a "no cost" basis data on intervening medical care and status. Since both the local physician and the hospital may have little current interest in this past history, we anticipate more difficulty here than elsewhere in

completing the patient's ASHD record. However, we will at least be able to compute accurately total survival time as well as know something about the final status regarding ASHD pattern development.

A corresponding inquiry, on screened dead patients, to the physician signing the death certificate will require adroit wording if we hope to obtain much useful information from him at this late date.

History Coverage Check

This whole transcription task depends, in its final value to the Navy and to persons interested in arteriosclerotic heart disease, on the careful accumulation of a uniform set of data on these ASHD patients and on a corresponding record (to the extent feasible) from a control group.

Because of the great variety of original data records making up the medical record and supplemental data sources to be used, it is very important that we have a careful check made on the completeness of each man's record prior to attempting to use the data. As mentioned previously, we are setting up an elaborate data control system to assure us that necessary information about each man has been provided as far as "feasible" and in the proper manner and place.

A further check is necessary however, to assure us that our knowledge of his ASHD history is really complete or nearly so. This is so because many of the patients whose records we will be looking at are now dead and have been for some time. Others, still alive, have Navy medical records which appear to be complete up to the final permanent retirement evaluation date, but with little or nothing

in the record since then. Still others have had subsequently recorded medical contact but we don't know how complete this is.

If we use "absence of information" or "absence of medical contact" in the record as "evidence" that the patient has had no further ASHD episodes, we may be led astray regarding the more recent status of these patients. Therefore it is planned to set up a check system to review the unaccounted-for periods of patients whose records are not recently active. This will provide a look at the patient's prior ASHD history, his status on retirement and the probabilities of his having had further episodes during the "uncovered period" for which we should provide some information. A review of these "history coverage" schedules will show us how complete are the data we are proposing to use and what we should do to complete them.

Recording Procedure

The straight-forward cases will be processed by a statistical clerk after he has demonstrated his ability to cope with the ground rules and his accuracy has been verified. Cases which give him difficulty will be set aside for review with the project analyst (for guidance) or later for completion by the latter. All recordings will be reviewed by the latter person as part of the episode summary briefing procedure. A continuous control check will be made of the actual data transcription to assure a low level of mechanical mistakes.

It is anticipated that the transcription task will require about six months for the full time of a statistical clerk and part time for the project analyst. The latter will provide for proper supervision of the data collection.

In addition to difficult cases, all obscure, complex or controversial cases, will be reviewed by the project analyst. If these cannot be clarified by the latter person, they will go to PQMR medical staff for panel agreement.

Time estimates of the necessary clerical time probably required for this recording — recently supplied to the Divisional Administrative Officer 1/ — are rough and are subject to substantial upward revision if the recording work does not run smoothly or if we encounter too many complex cases.

Briefing of Episode Summaries

As part of the data record for each episode, pertinent clinical details commenting on the history of the episode will be recorded by a clerk on forms 1 and 2. This material, one statement for each episode, will be summarized on the "History Summary Card" (Form #5) by the analyst with pertinent conclusive remarks. These summary cards will be used by the analyst and by PQMR medical staff as the basis for a number of medical classification decisions and, therefore, must be readily legible as well as being concise m/. Corresponding applicable dates, etc. will be recorded on the "ASHD History Coverage Schedule" (ASHD Form #7) by the clerk and will be reviewed by the analyst for their implications as to further steps required.

Physical Measurement Profiles

The clerk will record for each reference on a physical examination

1/In a document dated 9/13/62.

m/A provision, not yet arranged for, for typing labor for these summaries will also be required.

and for corresponding references on physical evaluation board, medical survey board, medical board or hospital clinical notes or admission summaries, the following items: height, weight, chest circumference at expiration, additional chest expansion on inspiration, blood pressure (sitting, immediately after exercise and 3 minutes after exercise), pulse (sitting) and examination date (or episode start date).

These values will be plotted if they appear casually to be irregular or unusual (expecially the episode start values) as a physical profile chart, in order to spot how much and which way the out-of line values are statistically abnormal. This will be done in order to supply estimates of weight, blood pressure, etc. at date points corresponding to episode starts (when the latter are too irregular for our use) and to supply signal points at which these values become medically abnormal. The latter would constitute "signal" dates whose occurrence we would attempt to correlate with concurrent or later onset of ASHD. Thus a point at which blood pressure (particularly diastolic) took a marked upward trend, beyond the established normal threshold point, would constitute a critical date to be related to a subsequent ASHD onset.

This profile arrangement will also help us spot data which have been incorrectly recorded. Thus a few heights are occasionally mis-recorded in the record by as much as 2" or 3" (one way or the other) deviating from the rest of the record. This device spots the mistake immediately.

Control Cards

As each project person records a unique section of data or finishes a necessary step, this is checked on the project control card with a date. We will thus be able to tell quickly what our progress is and where the principal bottlenecks are. A corresponding entry for certain data sources and dates will also be made on the ASHD history coverage schedule to ascertain the need for further follow-up.

Coding of Verbal Information

All data and information which is to be used for mathematical analysis must be coded — with the use of an agreed-upon number code with as few digits as possible for each item. No provision has been made in project staffing for this coding time since we hope to borrow such short-time need from other units of this Division or elsewhere in BUMED.

Calculation of Data Variables

Certain items, such as time intervals between 2 dates, are not readily calculated by automatic equipment. These probably will be computed by hand. However, many ratios, products and selected statistical test measures may be compiled easily by IBM equipment, such as the "604"; this means will be used whenever possible in order to save manpower. However, a certain minimum manual computation will remain and must be completed prior to card punching. Moreover certain other calculated data will be used in subsequent computations. These also will have to be hand computed.

Card Punch, Verification and Listing

This punching task can be performed by Data Processing Division during the coming winter and spring (1962-1963); we anticipate no difficulty in scheduling the operation. Machine lists would follow which also entail no anticipated difficulties. We estimate possibly 8 to 10 punch cards of data will be required for each heart case. Control cases will probably require only 3 or 4 cards each. This will result in the punching and processing of from 8,000 to 10,000 punch cards during the early spring of 1963 to be individually listed by major and minor groups and subgroups.

Preparation of Manual Cross-Tabulations on Basic Relationships

Inspection of the transcript cards, together with a few elementary handcounts, will determine which cross-tabulations are likely to be productive of useful data-relationships. At this point we propose the preparation of a small number of basic cross-tabulations by hand. These are intended as guides to more elaborate machine tabulations to follow and to give us a rough idea of the basic characteristics of the ASHD sample with which we are dealing. Such hand tabulations would probably include the following:

1. Age groups at last contact by ASHD pattern types;
2. Survival-time groups by age group at first ASHD contact;
3. Survival time groups by ASHD types;
4. Age at first episode (by age groups) by ASHD type;
5. Survival time by number and type of major episodes; and
6. Severity of episode by survival time.

The foregoing counts would include numbers of patients in each

category and some percentage distributions. They can be easily prepared from simple hand tallies of the involved groupings and would be the basis for preliminary correlation charts used to guide our subsequent work. They have the advantage of being flexible in composition and can be tried out on large sub-samples prior to transcribing and coding the whole sample.

Summary and Cross-Tabulations by Automatic Machine

We plan to ask Data Processing Division to supply summary tabulations by major groups and a large array of cross-tabulations by subgroups following the machine listing step above. This will be accomplished to specifications drawn by the analyst. These instructions would be devised also in conjunction with two-way correlation charts (based on large sub-sample data) which show interesting relationships.

Here again we anticipate no scheduling difficulty. This whole tabulation task should require no more than two full weeks of one man's time on a tabulator, not counting board-wiring time. The tabulations may be scheduled over a number of weeks so that the whole burden will not fall in one lump. They would probably need to be completed however, between April and June of 1963.

These foregoing machine tabulations will help to reveal which are the most significant relationships. From such information it will be decided (a) whether or not multiple regression analysis is a suitable further analytical tool to apply to the data, and (b) if so, what factors in what relationships to investigate further by this procedure. This stage constitutes the end of the Data Preparation Phase.

PHASE C: INTERIM REVIEW

Review and Stock-Taking

At this point a new project phase begins, (Phase C). Its schedule cannot be anticipated carefully at this point. We believe, however, that a month (possibly two or three) may be necessary to obtain a fresh outlook on where we are going and what the data probably might mean. This phase will be discussed in a following report next spring or summer.

Analysis Plan

From these foregoing machine tabulations and from the above-mentioned review, the final analysis plan will be prepared. It is anticipated that this plan cannot be provided at least until late spring or summer 1963, since its proper construction will require careful inspection of the completed transcript cards, correlation charts and machine tabulations. However, in general, the following aspects would no doubt be investigated as a basic part of the whole analysis:

- a) The character of the ASHD sample of heart patients;
- b) The character of the control sample, and its correspondence (in age distribution and selected other aspects) to the ASHD sample;
- c) Time distributions between crucial dates in ASHD history, including changes in corresponding administrative status;
- d) Survival time vs severity indices;
- e) Cross-distributions of the foregoing data in items (a),(b) and (c), by age group, severity group, survival time group, etc.

f) The minimum size of sub-group classifications which can be tolerated with statistically valid results and corresponding pertinent statistical measures.

ENCLOSURE 1

REVISED SCHEDULE OF ASHD DIAGNOSTIC PATTERNS

(For selection for statistical classification of patient status at beginning of first major episode).

<u>Code</u>	<u>Diagnostic Pattern</u>
0.	Fatal arrhythmia and selected cases of "sudden death" ^a (only those which can fairly definitely be ascribed to ASHD).
1.	Asymptomatic infarction (this diagnosis based on ECG evidence only).
2.	Angina pectoris.
3.	Prolonged (acute) coronary insufficiency.
4.	Myocardial infarction (symptomatic).
5.	Infarction (symptomatic) accompanied by congestive heart failure.
6.	Asymptomatic infarction (ECG evidence) at some prior period with subsequent overt episode of angina pectoris or any other pattern.
7.	Angina pectoris accompanied by congestive heart failure.

^a/Where there is more evidence than just a civil death certificate, without attendance by a physician familiar with the patient.

^b/Statistical treatment of 2nd episode of other patterns (other than anginal) will depend upon how many turn up.

Revised: 15 October 1962

ENCLOSURE 2

CRITERIA FOR ACCEPTANCE OF THE SEVERAL TYPES OF ASHD PATTERNS *

<u>Code</u>	<u>Situation</u>	<u>Comments</u>
0	"Sudden Death" (with fatal arrhythmia)	Excluded are all cases for which there is no evidence of any kind available. This evidence must come from observed symptoms, examination signs, ECG's, and/or autopsy. When prior weight and/or blood pressure records are abnormal, or other suggestive clues are available (but no real evidence), we will include the cases, but count them separately so that they may be treated differently, if necessary. All excluded cases, however, will be accounted for and described as part of the original sample. A death certificate signed only by a coroner or a doctor who has not treated the patient will not be considered "evidence".
1	Asymptomatic Myocardial Infarction (Based on ECG evidence only)	<u>Symptoms:</u> none admitted <u>Signs on Examination:</u> none <u>ECG:</u> shows pattern of recent or old myocardial infarction. If Masters Two-step test is "classically" positive, this is additional evidence (but must not be used alone). See Code 4 for ECG Q wave findings.

* See "Revised Tentative Schedule of ASHD Patterns" (Revised 15 Oct 1962).

<u>Code</u>	<u>Situation</u>	<u>Comments</u>
2	Angina Pectoris	<u>Symptoms:</u> Sudden onset following exertion, eating, emotion or exposure to cold; often accompanied by palpitation, faintness, dizziness, dyspnea, belching, fear of sudden death and sometimes orthopnea or nausea. <u>Signs:</u> Relieved by rest and/or nitrites (usually sublingual nitroglycerine); signs follow exertion-pain/rest-relief pattern; frequently also hypertension, cardiac enlargement, or valvular signs. Usually no temperature rise. <u>ECG:</u> Usually normal findings except during an actual attack or during an exercise test (such as Masters).* Abnormal ECG pattern during actual attack.
3	Prolonged Coronary Insufficiency (Acute) (Status Anginosus)	<u>Symptoms:</u> Anginal pain of long duration (More than 5 minutes), usually lasting from 5 to 45 minutes and usually less than one hour; not classically relieved by nitroglycerine; sometimes other symptoms noted for angina pectoris, such as faintness, dyspnea, etc. <u>Signs:</u> Temperature rise is more likely than with angina pectoris, but is less frequent than with myocardial infarction.

* Classical angina pectoris ECG signs are given in note on last page of this enclosure.

<u>Code</u>	<u>Situation</u>	<u>Comments</u>
		Response to nitroglycerine and/or rest is much less sharp -- often no response. "The signs are temporary and nonprogressive". * <u>ECG</u>: Shows ST segment depression, with or without T wave inversion;** <u>abnormal</u> Q waves are absent. (AMA: shows elevated S-T waves.) *
4	Myocardial Infarction (Symptomatic)	<u>Symptoms</u>: Usually a prior anginal attack; <u>may</u> progress through an acute prolonged coronary insufficiency stage; lasting much longer, however (usually 1 to 8 hours) and frequently requiring morphine for relief. Sudden, severe, protracted substernal compression with pain, radiating to arms, neck, abdomen or jaw; and sometimes with dyspnea, weakness, nausea and vomiting. <u>Signs</u>: Slight elevation in temperature (from + 0.4°F to + 2.0°F); nitroglycerine usually gives no response; morphine usually does.

* AMA document, Current Medical Terminology, 1963 (Chicago, 1962)

** These may be transient.

<u>Code</u>	<u>Situation</u>
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4	continued
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<u>Comments</u>

Signs: frequently there is rapid shallow respiration; hypotension and/or shock; weak or thready pulse; arrhythmias; premature contractions; gallop rhythm; ventricular paroxysmal tachycardia; basal pulmonary rales.

Laboratory: High white cell count, elevated sedimentation rate and high serum enzyme levels (SGOT).

ECG: The ECG evidence must be explicitly stated by the doctor as a "myocardial infarction" (or some variant of this terminology). This evidence is usually obtained from serial examination of ECG tracings, compared over several days' series of ECG tests. The ECG signs are:

- (i) Peaking of T wave (from a lead opposite the infarction area)
- (ii) Lowering or inversion of a previously upright T wave;
- (iii) Change in ST segment position (slight - 1 mm. or more - elevation or depression); a depressed ST segment is shown from lead opposite to the infarction area.

<u>Code</u>	<u>Situation</u>	<u>Comments</u>
		(iv) appearance of deep, abnormal Q or QS wave *, <u>the most characteristic ECG finding in an infarction.</u>
		When this evidence is <u>not</u> present *, other ECG and non-ECG evidence must be used. The Q wave usually endures for the rest of the patient's life and is, therefore, the signal also of an old infarction -- as well as of recent or current ones.
		When the foregoing ECG signs are from lead 1 the infarction is anterior, when from lead 3 and often lead 2, the infarction is posterior. Two-thirds of the cases usually are posterior -- only one-third anterior.
5	<u>Congestive Heart Failure and Myocardial Infarction</u>	The symptoms, exam signs, lab data and ECG signs are those of Code 4 above (myocardial infarction) plus the following additional for the congestive failure: <u>Symptoms:</u> Exertional dyspnea, paroxysmal nocturnal dyspnea, weakness, cough and orthopnea.

* In the presence of left bundle branch block, the diagnosis must be made on clinical/laboratory grounds without the ECG findings.

<u>Code</u>	<u>Situation</u>	<u>Comments</u>
5	Continued	<u>Congestive Heart Failure:</u> Signs: Enlarged heart ; pulmonary "congestion" or "edema" and/or effusion with stress on presence of inspiratory rales; Cheyne-Stokes breathing; orthopnea; ascites; venous distention, including engorged neck veins; general edema, including evidence of sudden gain in weight or an electrolyte increase; increased venous pressure (above 140 mm.); irregular pulse; diastolic gallop rhythm; enlarged liver; weaker heart sounds; slow blood circulation time. <u>Laboratory:</u> Oliguria; albuminuria; urine hyaline casts; increase urine specific gravity. <u>X Ray:</u> Shows pulmonary congestion and/or increased lung field density.
6	Asymptomatic infarction (ECG Evidence only) on an earlier nonrecorded episode -- followed by a second <u>overt</u> episode of angina pectoris*	This pattern has been selected to provide for a few such cases appearing among Navy ASHD patients. The evidence of the first episode is only from ECG findings (see Code 4 for the description of Q wave abnormality which persists)

*It is possible that we may have some cases where the second overt episode is an infarction rather than angina. (Substitute code 4 signs, in place of code 2, in this case.)

<u>Code</u>	<u>Situation</u>	<u>Comments</u>
6	Continued	but may be occasionally verified by the patient in retrospect. Criteria for second episode of angina pectoris following those described under Code 2, above.
7	Angina Pectoris accompanied by Congestive Failure	This pattern combines criteria for angina pectoris (Code 2, above) plus those for congestive failure described for that condition alone under Code 5 above.

Note (1). There are, theoretically, a number of additional patterns exhibited by this disease. Most of them, we believe, either occur too infrequently to allow dealing with them statistically or they occur in other age groups than included in the Navy group. One type asymptomatic ASHD, without myocardial infarction — was considered in our planning but was discarded as occurring too infrequently. However, this type will no doubt appear more frequently among more recent cohorts — those for 1955 or later. When such samples are examined, we shall probably need to add this variant to our list. The ECG signs (the only signs available) are those for classical angina pectoris following exertion and are revealed by a Masters Two-Step Test.

Note (2). Classical angina pectoris ECG findings are obtained only during an actual attack or during a Masters or other exercise test. They are the following: T wave inversion with or without ST depression (or flattening); frequent ventricular extra systols; right or left bundle branch block; auricular fibrillation; positive Masters test

("Double" if not positive on "Single" test). When asymptomatic ASHD is present, the ECG findings must show either positive "angina" findings (as above) on Masters Test or infarction pattern evidenced by abnormal Q wave residue.

ENCLOSURE 3

DATA ITEMS PROPOSED FOR TRANSCRIPTION: ASHD

(a) Essential Items Related to ASHD

- * 1. Serial no. (7 digits)
 - * 2. Study no. (3 digits)
 - * 3. Birthdate (6 digits)
 - * 4. Age at entrance (2 digits)
 - * 5. Age at death or at last BuMed contact (2 digits)
 - * 6. Activity status now (dead; or if alive, degree of present activity apparently allowed) (1 digit)
 - 7. Number of major episodes (1 digit)
 - 8. Character of each episode (Separate punch card for each episode)
 - a) Count of episode (1st, 2nd, 3rd, etc.) (1 digit)
 - b) Episode pattern (1 digit)
 - c) Confirmed diagnosis (4 digits)
 - d) Age at episode start (2 digits)
 - e) Bed rest required during episode (in days from adm. date) (3 digits)
 - f) Time lapse from beginning of episode till beginning of next episode (or to present date)^{a/} in months (and fractions) (2 digits)
 - g) Disease complications of each episode (10 columns)
 - h) Symptoms and tests for each episode (18 columns)
 - i) Blood pressure on admission (6 digits)
 - j) Blood pressure later (in first three days) if there is a radical change either way (6 digits)
 - k) Pulse (sitting, before exercise) (3 digits)
 - l) Temperature (if elevated) (1 digit)
 - m) Weight/height index (3 digits)
 - n) Sed rate at maximum (2 digits)^{b/}
 - o) Cholesterol value at maximum (3 digits)^{b/}
 - p) White cell count (in thousands and fractions) at maximum (3 digits)^{b/}
- (Note: These item 8 entries add to 71 digits altogether for each episode.)

^{a/} In the event that patient has not had further apparent episodes.

^{b/} These items are infrequently reported in Navy medical records.

* Items for which data may also be obtained from the controls.

- * 9. Rate or rank at end of first episode (2 digits)
- *10. Date of TDRL (4 digits)
- *11. Date of Perm. Ret. (4 digits)
- *12. Prior VD Record (6 digits)
- *13. Retirement status at death or last BuMed contact (1 digit)
- *14. Apparent survival time (from 1st episode start to death or last BuMed contact). (2 digits)
- 15. Reciprocal of item 14: (index of severity) (2 digits)
- 16. American Heart Assoc. Class. (Therapeutic) (1 digit)
- 17. American Heart Assoc. Class (Functional) (1 digit)
- *18. Prior ASHD, cardiac and CV record at beginning of each episode

(b) Physical Examination Measurement Data

- *1. Date (4 digits)
- *2. Height (3 digits)
- *3. Weight (3 digits)
- *4. Weight/height index (3 digits)
- *5. Normal weight for height (3 digits)
- *6. Normal index (3 digits)
- *7. Excess weight index (2 digits)
- *8. Chest (at expiration) (2 digits)
- *9. Expansion over expiration (1 digit)
- *10. Build type Index (chest expiration/height) (2 digits)
- *11. Blood Pressure (Sys/Diast) (6 digits)
- *12. Pulse (sitting, before exercise) (3 digits)

* Items for which data may also be obtained from the controls.

A separate graph will be prepared for each of these index measurements which casually appear irregular - constituting a time series for this patient. Critical points on the chart will be spotted and the chart will be used for estimating missing data as well as to earmark the probable crucial points and the incidence of early stages of ASHD, if possible.

(c) Optional But Desirable Additional Items

- | | |
|------------------|---------------------------------|
| * 1. Birth state | *1. (a) Present residence state |
|------------------|---------------------------------|
2. Years of service at each episode (to be added to each episode card if space allows)
 3. Rank or rate at first episode only
 4. Duty station each episode (coded by characteristic type or actual identification if space allows)
 5. Hospital identity for each episode
- * 6. Job activity just prior to first episode (to be obtained from BuPers)
 - * 7. Battle stress exposure prior to first episode (prior 3 years) (from BuPers)
 - * 8. Apparent Smoking record
 - * 9. Apparent Alcohol record
 - *10. Allergies (if any)
 - *11. Respiratory infection record (Has patient had record of frequent colds, flu, etc.)?
 - *12. Skin Infection record (ditto for skin infections)
 - *13. Accident proneness (Count recorded number)
 - *14. Prior diseases (other than ASHD, VD, Heart and CV)
 - *15. Prior special disease record (diabetes, etc.) and familial history of diabetic, cardiac, or hypertension disease.
 - *16. Apparent Survival Time (time lapse in years & fractions from each episode to death or last BuMed contact). This to go on each episode card if space allows, otherwise on main card for last episode only.
 - *17. Apparent exercise activity (athletics, etc.)
 - *18. Apparent adjustment (or lack) to Navy life and job/rating/rank
 - *19. Any psychoneurotic clues, neuroses, etc. (evidence)

TAB A: DESCRIPTION OF BASIC SAMPLE, ITS LIMITATIONS
AND THE CONTROL SAMPLES

Original Sample Size

This sample of 552 ASHD cases was provided from a list of persons with "F cards" (hospital admission punch cards originally collected by BuMed Data Processing Division for annual central office statistical reporting) with the ASHD admission diagnoses of 4700, 4701, 4702 ^{a/}, appearing in central office records for 1950 and 1951 only. It excludes cases with these diagnoses appearing earlier or later. With few exceptions, these patients were permanently retired in 1955 - 56 or occasionally earlier. Some of these undoubtedly have had hospitalizations subsequent to 1956 which are not documented in the PQMR medical record file. This will require checking and supplementation, where our record is not complete, from local doctor's or local hospital records.

Consequent Use Limitations

We are planning a rather elaborate cross-tabulation series from data on these patients together, possibly, with correlation/regression analysis of a substantial portion of this complex data collection. For this purpose, a much larger sample would have been derivable. However, this is not feasible currently if we wish to extend our examination of the ASHD history data to at least a 10 year follow-up period. For this reason, we have accepted this small sample size as a basic limitation and propose to use the data

^{a/}There were a few additional cases with diagnosis codes 4703 and 4704, but these were merely terminology variations of 4700, 4701, or 4702.

only in a manner consistent with this size limitation.

In order to get around this restriction in the future, we are considering making this study a periodic operation and adding further cohorts of patients showing ASHD "F card" admissions in years subsequent to 1951. These additional cases could be processed later for a further five-year follow-up as part of this current study or we can wait several more years before attempting a 10-year follow-up on them. These additional data would then be added to the current series at that future time.

Current Sample

The current sample of 552 cases includes data on 219 officers and 333 enlisted men ^{b/}who first showed ASHD admission diagnoses in 1950 or 1951 (see note on the previous page). Duplications in count between the two years have, of course, been eliminated; the names and identifying numbers represent first admission only. These ASHD cases were taken from a Navy membership "population" of the following magnitude:

Average Annual Strength During 1950 and 1951

<u>Year</u>	<u>Total Strength</u> <u>(Navy and Marine Corps)</u>	<u>Officers</u> ^{c/}	<u>Enlisted</u> ^{d/}
1950	538,179	63,924	474,255
1951	915,024	90,023	825,001

^{b/}The sample was obtained in 1960 by a BuMed division which was later reorganized into the present Data Processing Division. Records pertaining to this selection technique are somewhat obscure. However, we think we have reconstructed the selection history fairly carefully.

^{c/}Including candidates-for-officer.

^{d/}Including prisoners.

Reference to the foregoing figures and to Table I (see next page) show that during this two-year period, naval manpower strength rose about 70 percent from 1950 to 1951. This increase was brought about by the needs of the Korean War which started in June 1950. The number of enlisted men were increased somewhat faster, at 74 percent, while the increase in officer ranks was only 41 percent.

In contrast, total ASHD admissions rose 22 percent between 1950 and 1951 -- the rise occurring entirely among enlistees (60 percent) whereas ASHD officer new cases actually declined between these two years (19 percent).

Questions Raised By These Rates

These comparisons raise some questions. Was there any change in recognition standards or in diagnostic or hospital admission standards occurring between 1950 and 1951? If so, how did these differ between officers and enlisted men? Casual inspection of the hospital admission rates per 1,000 men strength (Table I) might suggest that the standards for ASHD admission were tightened somewhat during these two years -- slightly for enlisted men, but quite drastically for officers. However, it must be remembered that nearly all the new officer strength were young men, most of them from a reserve status already carefully screened for ASHD.

During a period of rapidly expanding Navy strength -- at a time when officers were not being trained as fast as the need for them increased -- this foregoing officer/enlisted differential might be expected to some extent. However, the degree to which this change apparently occurred seems unusual.

Table 1: Navy and Marine Corps Strength
and First Admissions for ASHD: 1950-1951

Strength			
Item	1950 Strength	1951 Strength	Average Level
Total	<u>538,179</u>	<u>915,024</u>	<u>726,601</u>
Officers	63,924	90,023	76,973
Enlisted	<u>474,255</u>	<u>825,001</u>	<u>649,628</u>

First ASHD Admissions

Total	<u>249</u>	<u>303</u>	<u>276</u>
Officers	121	98	109
Enlisted	<u>128</u>	<u>205</u>	<u>167</u>

Rates of Admission: Per 1,000 Strength

Total	<u>0.462</u>	<u>0.331</u>	<u>0.380</u>
Officers	1.895	1.089	1.416
Enlisted	<u>0.270</u>	<u>0.248</u>	<u>0.257</u>

Percent Changes: 1950 to 1951 (Based on 1950 = 100)

<u>Strength</u>		<u>Admissions</u>	
Total	70.0	Total	21.7
Officer	40.8	Officer	- 19.0
Enlisted	73.8	Enlisted	60.0

SOURCE: 1950 - 1951 "Annual Reports of Navy Medical Statistics" and a special count of corresponding 1950 - 1951 ASHD Admissions. The latter are subject perhaps to some slight readjustment between officer and enlisted ASHD cases in addition to some slight adjustment in total count, after a thorough review of all of them is completed. 4A

Was there a change in definition between these two years which would account for part of this effect? A change occurred in official nomenclature between 1948 and 1950 which might not be fully reflected in practice until 1950-1951. The result of this effect will be investigated and discussed at a later time when we have more facts. Likewise, comparable figures for 1951 and 1952 will be explored.

Nonrepresentativeness of Naval Population Generally

The sample of 1950-1951 ASHD cases occurred, moreover, among a Naval population representing a very highly selected body of men of much-above-average fitness at the time they first entered or reentered the Navy. Naval incidence of ASHD, compared with a correspondingly age-distributed civil population, may well be drastically affected by this selectivity.

In contrast, these men on the whole were possibly better fed than a corresponding civil population. Other studies suggest apparently that well-fed populations show more ASHD than those with restrictions in diet; this effect, if operative, may work in an opposite direction to the original fitness screening.

Types of Data Readily Available

There is a wealth of certain types of data which, if properly used, should be an abundant source of information for analysis of questions relating to ASHD-induced disability and retirement. Some of this material also may apply to entrance and continuation-on-duty questions as they are influenced by possible development of ASHD. This latter type of information may also have significance generally in epidemiological questions related to ASHD, i.e., defining the

natural history of the disease.

These data areas are: incidence and prevalence of high pulse, hypertension and obesity (in relation to age of the patient); the relation of body-build to ASHD development; the relation of any of venereal, respiratory and other infections to ASHD; familial cardiac, diabetic and hypertension history; use of anticoagulants, vasodilators, sedatives and narcotics; standard ECG recordings for suspected and established ASHD cases; effect of weight reduction programs in management of angina pectoris and post-infarction cases; and the adjustment (by age groups) of ASHD patients to ASHD restrictions in activity, economic status and apparent mode of life.

Incompleteness of Some of the Types of Data

Relatively little information is available from our proposed sources on individual choice of diet and quantity of food consumed, but we feel weight changes may be an indirect clue to these items. Other apparently important items on which we have little information of record are: relative consumption and manner of alcohol and tobacco usage; relative extent of worry, emotional strain, etc.; and the character of adjustment of the individual to restrictions and stresses created by the long periods at sea, to combat area stresses and to mobilization-demobilization stresses. We know practically nothing about marital and related social adjustment except the member's outward marital status and occasional comments elicited by the attending physician.

Likewise, we have few references in the hospital records to the more recent innovations in ASHD-related laboratory techniques, particularly among the controls. These innovations are tests such as enzyme levels, e.g., (transaminase), blood cholesterol level and other blood lipid changes. Records of hematocrit and lacto-dehydrogenase values are generally not available. Erythrocyte sedimentation rates and white cell counts are not recorded as frequently as one would desire -- especially in the earlier part of the 1950-1960 decade. ECG recordings generally were made only on persons known or suspected of having ASHD -- seldom on controls (except for officers over 45 years of age and more recently for candidates and members in aviation branches of the service). Usually, ECG recordings were isolated records -- rather than complete series -- except where the

patient was an infarction case or had some very serious cardiac disorder, such as congestive heart failure, arrhythmias, etc.

Routine Masters single and double two-step ECG tests were performed only for doubtful ASHD cases about which serious question was held as to the disease status. For obvious reasons these tests are not as generally available as one might desire on all simple angina pectoris and prolonged coronary insufficiency cases, nor are they available serially for follow-up on healed old-infarction cases for which the doctor anticipated the possibility of continued angina or other relatively mild ASHD symptoms.

Need for Additional Cohorts From Later Years

Rapid advances have been made in diagnostic and therapeutic techniques in the treatment of ASHD in recent years and further advances will probably occur. We intend to incorporate in our procedure some later extensions which will reflect these changes. These extensions would add later cohorts (1952 and subsequently) to the sample array when feasible. We are also planning now for provision of additional types of data collection later, e.g., SGOT levels, cholesterol levels, etc., as well as for expansion of the sample size. Our efforts at this point will be directed toward adequate planning now so that such extensions to sample size and to data items and changes to the analysis technique may be made later if they are deemed feasible and desirable.

Effect of Additional Cohorts

It would be desirable to have a larger total heart sample for study. Moreover, it would be of great interest to bring into the

study, representation from patients who developed the disease in more recent years than 1950-1951. This introduction would automatically cut down, however, on the follow-up time available to such additional cohorts.

We feel the additional worth to be obtained from them would justify the additional burden later, and would compensate for the shorter follow-up time. Information on newer treatment techniques as well as the newer diagnostic laboratory tests would be available. Therefore we will, if administratively feasible, develop a technical procedure which will allow for their introduction -- following the transcription job completion for the 1950-1951 series. If the clerical time is available next spring, data for them will be added to the study file at that time. Analysis of these data may be postponed until a later date. This addition would impose a transcription coding burden as large as or possibly somewhat larger than the present one if we included data for the cohorts for the years 1952-1953 or some later pair of years.

The Problem of Selecting the Control Sample

Need for Controls

We need a control sample of persons who represent as nearly as possible a cross-section of Navy health -- one sub-group for officers and another sub-group for enlisted men. These controls would be used for comparisons of physical and medical data with corresponding data from the heart patients.

Idea Controls

These two control groups should each show the full age-range and approximately the same age-distribution as the major population groups from which they are drawn. Ideally, the health record of the sample should have the same range and proportions of sickness, dispensary visits, hospitalizations, etc. as represented by the parent group (a generally healthy population). However, for enlisted men, particularly since the great bulk of the Navy enlisted strength is in young men in very good health, a random sample may show relatively few hospitalizations, except for accidents and for the most minor conditions requiring medical treatment. With even a large original random control panel to draw from (say from 800 to 1,000 enlisted men), we would probably obtain relatively few non-accident hospitalizations.

It is possible that such a procedure would provide a "control" sample ^{d/} of non-heart "sick persons" of so small a total by age group (out of a generally healthy random panel) that no valid detailed statistical conclusions could be inferred from comparing hospitalization records of these persons by age groups with corresponding records for similar age groups among the heart patients.

We shall obtain for, our comparison, those items provided for all members (well or not) and, therefore, available from the controls as well as from heart patients. These are: weight, height, and chest data (and similar other routine physical measurements) -- together with blood counts, x-ray, and certain usual laboratory tests (given

d/ That is, a randomly chosen sub-sample from a larger randomly chosen panel.

in all physical examinations)^{e/}.

Need for More Instances of Hospitalization

The nature of some of the questions needing answers require comparison of the results of additional data normally obtained only for more serious types of hospitalized illnesses. If so, then such a small random sample will probably be insufficient. This may well be the case particularly at the lower end of the age distribution where the Navy health is generally good and relatively few non-accident hospitalizations occur.

We will then need to reinforce the originally proposed control sample to a sufficient total size to obtain from it approximately the same number of hospitalizations as among the heart group. From such a larger "random control panel" we can randomly select a hospitalized control group for which we will attempt to provide data by age groups for as many as possible of the same items as will be provided for heart patients.

A possible secondary limitation in such a hospitalized control group concerns the statistical treatment of included accident cases. These represent a large proportion of the Navy's hospital load. They constitute, however, somewhat different type of hospital care than do heart patients. Physical, clinical and laboratory data on such patients would not be comparable generally with corresponding data for hospitalized heart patients. This problem has yet to be solved in a wholly satisfactory manner.

^{e/}ECG's are only given routinely for aviation members and for officers of more than 45 years old; likewise certain of the laboratory tests are requested only for heart patients and are not routine.

Automatic Selection of Control Panel

Since the original random sampling of the Navy strength and the further random sampling of hospitalized non-heart patients can presumably all be done by automatic procedure with IBM cards, we do not anticipate any great additional burden required by the foregoing sample reinforcement and sub-sampling procedure. However, it will require carefully prepared instructions for the automatic machine work. The real burden imposed by the use of control sample lies in transcribing the additional data for the hospitalized patients among this group to our proposed project record sheets.

It is proposed that a tabulation of the larger control panel be prepared, if possible, prior to the selection of the final non-heart hospitalized sub-sample. This tabulation should show several comparable distributions, one set for the control panel and a corresponding set for the whole Navy strength. The latter might be obtained presumably from routine standard tabulations already prepared or now in process.

It will, of course, be necessary to know the real morbidity and mortality incidence rates in both non-heart and heart groups. These data can, of course, be computed.

TAB B. SPECIFIC TYPES OF DATA TO BE EVALUATED

For Computing Critical ASHD Time Intervals

In order to compute a whole series of important time intervals related to the development of ASHD, the following dates are needed: date of birth ("age")^{a/}, date of Navy entrance ("years of service"); date of first warning signal ("years free from ASHD" and "years from first warning"); date of first overt major episode ^{b/}("survival time-total" and "years to initially develop the disease"); date of each subsequent episode ("months between episodes" and "sub-survival times"); dates of each bed-rest beginning and end ("days of recovery" - an inverse severity index).

For Computing Intervals of Time Associated with Actual Status Decisions

In order to compute time intervals relating to actual administrative decisions on ASHD patient status, the following dates are needed: dates of each decision by a Medical Board, Medical Survey Board, or Physical Evaluation Board, and by Bureau of Personnel, Bureau of Medicine and Surgery, Headquarters of US Marine Corps, the Judge Advocate General and/or The Secretary of the Navy regarding ASHD patient's status and the rating allowed with this decision. The latter are needed in order to count the numbers of each type of case which were changed in line with the disease development and the number out of line with its development. The decision time intervals would be compared with the

^{a/}Data in parenthesis are the critical time intervals.

^{b/}We shall have to decide whether this first episode need be under direct Navy BuMed observation or not.

disease development time intervals to determine which of the former correspond with the latter and whether the re-evaluation procedure can be effectively shortened.

Points from which timing would be centered are: first major ASHD episode, first ASHD confirmed diagnosis, TDRL date, first re-evaluation date, date of each subsequent re-evaluation, date of final permanent retirement, date of death or last contact.

Counts by disability rating groups would show proportions, for each ASHD pattern, of those that remained unchanged, of those increased and of those decreased. For each of these subgroups, we could then determine which were confirmed by hind sight and which were not.

If possible, it would be desirable, for each ASHD diagnostic pattern, to determine at what earlier date than that actually used, a conclusive decision could be made on the basis of all data available or of significant portions of it.

Frequency of Occurrence of Each Type of ASHD Episode ^{c/}

For this purpose, data necessary to supply the following other factors are needed: age groupings, groupings by years of service, by member classes (officers or enlisted men, ASHD patients or controls), by rank/rate classes, by duty status now and at end of 1st episode, by state of birth, by duty location prior to first episode, by duty location at last episode, by number of episodes, by activity status now (type of work status and activity allowed medically), by American Heart Association functional and therapeutic indexes, by severity

^{c/}Perhaps the investigation may suggest that one episode alone is not sufficient for a status determination and that a series is required.

status indexes based on reciprocals of bed rest time and survival time, by ASHD complication groupings, by Navy activity/experience factor classes, by patient symptoms and laboratory test groupings, by medication and anticoagulant groups, by "build" index group, by blood pressure/pulse groups, by socio-familial factor groups, and by sequence, severity and recurrence-rapidity groupings.

Additional Factors To Be Explored

Although we will not be able to obtain any large quantity of valid quantitative data on certain items, it will perhaps be possible to say whether the following factors are "operating" or "not operating" (or "present" vs "absent"). These are: combat area stress experience; smoking/alcohol use; accident proneness; presence of diabetes, allergy, familial heart disease and/or hypertension; use of anticoagulants (and type); and early or late ambulation.

In addition, it is possible that we may be able to say something about the evidence from special tests such as serum cholesterol, of serum lipid, hematocrit, SGOT, Masters two-step ECG, etc. However, this is extremely unlikely because of the paucity of such data during the early years of the 1950-60 decade. These tests were new in 1950-1951 or had not yet been introduced. Relatively few references to them occur for those early years. Perhaps analysis later from data from subsequent years will throw light on these points.

Specific Data Items to be Transcribed

We are now testing the transcription forms which have been devised for this task. Examples of these, together with specific lists of data items to be recorded, are discussed elsewhere in this plan. Since

only 25 ASHD cases have been informally recorded so far ^{d/}we do not yet know whether all the items proposed on these foregoing lists and in the recording forms can be uniformly and consistently obtained. We think most of them can. Some of them, however, may have to be dropped from the final transcription task for lack of unambiguous data.

^{d/}Although 100 cases have been casually inspected.

